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12/ RCE 116158
Reg under 1.114

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REQUEST FOR CONTINUED EXAMINATION (RCE) TRANSMITTAL

Subsection (b) of 35 U.S.C. § 132, effective on May 29, 2000,
provides for continued examination of an utility or plant application
filed on or after June 8, 1995.

See The American Inventors Protection Act of 1999 (AIPA).

Application Number	09/AG3,42
Filing Date	10/20/1999
First Named Inventor	T. SHIMIZU
Group Art Unit	16002900
Examiner Name	S. Tran
Attorney Docket Number	2535 USOP

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FEB 21 2001

4-30-01

This is a Request for Continued Examination (RCE) under 37 C.F.R. § 1.114 of the above-identified application.

NOTE: 37 C.F.R. § 1.114 is effective on May 29, 2000. If the above-identified application was filed prior to May 29, 2000, applicant may wish to consider filing a continued prosecution application (CPA) under 37 C.F.R. § 1.53 (d) (PTO/BI/29) instead of a RCE to be eligible for the patent term adjustment provisions of the AIPA. See Changes to Application Examination and Provisional Application Practice, Final Rule, 65 Fed. Reg. 50092 (Aug. 16, 2000); Interim Rule, 65 Fed. Reg. 14865 (Mar. 20, 2000), 1233 Off. Gaz. Pat. Office 47 (Apr. 11, 2000), which established RCE practice.

1. Submission required under 37 C.F.R. § 1.114

- a. ☒ Previously submitted
- i. ☒ Consider the amendment(s)/reply under 37 C.F.R. § 1.116 previously filed on Feb 22, 01
(Any unentered amendment(s) referred to above will be entered).
- ii. ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____
- iii. ☐ Other _____
- b. ☒ Enclosed
- i. ☒ Amendment/Reply
- ii. ☒ Affidavit(s)/Declaration(s)
- iii. ☐ Information Disclosure Statement (IDS)
- iv. ☒ Other Free Transmittal; Return Postcard

2. Miscellaneous

- a. ☐ Suspension of action on the above-identified application is requested under 37 C.F.R. § 1.103(c) for a period of _____ months. (Period of suspension shall not exceed 3 months; Fee under 37 C.F.R. § 1.17(i) required)
- b. ☐ Other _____

3. Fees

The RCE fee under 37 C.F.R. § 1.17(e) is required by 37 C.F.R. § 1.114 when the RCE is filed.

- a. ☒ The Director is hereby authorized to charge the following fees, or credit any overpayments, to Deposit Account No. 500799
- i. ☒ RCE fee required under 37 C.F.R. § 1.17(e)
- ii. ☒ Extension of time fee (37 C.F.R. §§ 1.136 and 1.17) 04/12/2001 CEHAWI 00000076 500799 09403429
- iii. ☐ Other _____ 01-FC:115 110.00 CH
- b. ☐ Check in the amount of \$ _____ enclosed
- c. ☐ Payment by credit card (Form PTO-2038 enclosed)

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

Name (Print/Type)	MARK CHAO	Registration No. (Attorney/Agent)	37,293
Signature	<i>Mark Chao</i>	Date	4-10-01

CERTIFICATE OF MAILING OR TRANSMISSION

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner For Patents, Box RCE, Washington, DC 20231, or facsimile transmitted to the U.S. Patent and Trademark Office on:

Name (Print/Type)	MARK CHAO	Date	4-10-01
Signature	<i>Mark Chao</i>		

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02 FC:179 710.00 CH

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 09/403,429
Filed: 10/20/1999
1st Inventor: SHIMIZU, T.
For: Rapidly Disintegrable Solid Preparation
Atty. Dkt. No. 2535 USOP

Art Unit:
Examiner:
Allowed:
Batch:
Paper No.:

14/ Pre Response
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Preliminary Amendment/ Reply in RCE

BOX AF
Assistant Commissioner for Patents
Washington, D.C. 20231
Sir:

In response to the Examiner's Advisory Action Mailed March 13, 2001, Applicant's herewith submit the following Reply and Declaration along with a Request for Continuing Examination (RCE) and the appropriate fees.

REPLY

Applicant's thank the Examiner for withdrawing all rejections of the claims under 35 U.S.C. §102.

Claims 1-7 and 13-19 remain rejected under 35 U.S.C. §103(a).

Applicants herewith submit the Declaration of Mr. Shimizu describing results of an experiment directly comparing the properties of two formulations, conducted under the direction and supervision of Mr. Shimizu.

Formulation A (identified as Example A in the Declaration of Mr. Shimizu) was an orally disintegrable tablet containing low-substituted hydroxypropyl cellulose (L-HPC) according to the claimed invention. This formulation consisted of about 5.0 to 7.0% hydroxypropoxyl group, lansoprazole, erythritol and crystalline cellulose.

Formulation B (identified as Example B in the Declaration of Mr. Shimizu) was an orally disintegrable tablet containing low-substituted hydroxypropyl cellulose (L-HPC) described by Ohno et al. with the addition of lansoprazole as an active ingredient. This formulation consisted of over 7.1% hydroxypropoxyl group (more specifically 11.8%), lansoprazole, erythritol and crystalline cellulose.

While both formulations had suitable strength, the comparative results show that Formulation A had superior disintegration time and was subjectively preferred over that of Formulation B.

Hardness was determined using industry acceptable testing standards on a tablet hardness tester (manufactured by Toyama Sangyo Co. Ltd. Japan). The hardness test was performed in 10 runs, and the mean values shown in the results table on page 7 of the Declaration of Mr. Shimizu. There was little difference in hardness between composition A and composition B.

Oral disintegration time was determined *in vivo* using a panel of two male and two female testers. Disintegration time was measured from the moment of placement of the tablet on the tester's tongue, until disintegration, without chewing. The results are shown in the table on page 7 of the Declaration of Mr. Shimizu. As shown by the data obtained, the disintegration time of Composition A was far superior than that of Composition B (Average of 29 sec. v. 54 sec. respectively).

Contemporaneously with the disintegration measurement, the testers recorded their subjective opinion as to the oral properties of the disintegrating tablet and rated the quality as chalky (poor), slightly chalky, not chalky (good). These results are reported in the table on page 7 of the Declaration of Mr. Shimizu. Composition A was graded superior to that of Composition B (not chalky v. slightly chalky taste respectively).

The combination of Ohno et al. in view of Shashoua et al. do not teach or suggest the required modifications to arrive at the claimed invention, or any motivation to do so. The results reported in the Declaration of Mr. Shimizu directly comparing the formulations, show that the formulation of Ohno et al. could not suggest or reasonably predict the claimed invention because of the poor disintegration time and chalky taste obtained with Formulation B.

The combination of Ohno et al. in view of Shashoua et al. do not teach, suggest or reasonably predict success in obtaining the claimed invention. The results reported in the Declaration of Mr. Shimizu, directly comparing the formulations, support the Applicant's argument for the patentability of the pending claims and overcome the Examiner's remaining basis for rejection. The results show that the asserted combination of art fails to teach, suggest or reasonably predict the success of obtaining the claimed invention having the desired disintegration time and no chalky taste.

The rejection should be withdrawn.

Conclusion

Early allowance of the claims is requested. Should the Examiner believe that a conference with applicants' attorney would advance prosecution of this application, he is respectfully requested to call applicants' attorney at (847) 383-3372.

Respectfully submitted,



Dated: April 10, 2001

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